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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,318	11/07/2001	Erik Leonard Hoffman	05032-00011	4521

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John P. Iwanicki
BANNER & WITCOFF, LTD.
28th Floor
28 State Street
Boston, MA 02109

EXAMINER

COMSTOCK, DAVID C

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,318

Applicant(s)

HOFFMAN, ERIK LEONARD

Examiner

David C. Comstock

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 29-33 are objected to because of the following informalities: Method claims should recite active steps, e.g. "sawing, driving, positioning, abutting," etc. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-26 are directed to non-statutory subject matter.

Claims 16-26 positively recite the combination of the fastening device and bone. As such, the claims are considered to claim a human being which is considered to be non-statutory subject matter. A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-3, 5, 6, 10, 11, 13, 14, and 27-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Vincent et al. (5,007,935).

Vincent et al. disclose a fastening element comprising a supporting element 11, a largely hollow pin 6 extending from the supporting element, and a screw tensioning and fixing means 8,15' (see Fig. 2). The supporting element is plate-shaped where it contacts the bone and extends on two sides of the longitudinal axis of the pin. The pin is at an angle to the main surface of the supporting element. A coupling element 40 is positioned on the other side from the pin and is angularly offset from the longitudinal axis (see Fig. 4). The cross-section of the pin 6 has a multi-angular shape (see Fig. 1). The surface of the device is treated so as to promote bone ingrowth (see col. 2, lines 54-56 and col. 6, lines 11-19). Vincent et al. also shows a method comprising subcapitally sawing off a femur 7 and driving the pin into the bone at an angle with respect to the load-bearing surface. The pin is fixed from a cortical bone to the fastening element remotely from the abutment surface (see Fig. 2 and col. 2, lines 39-56). A template 73 having holes 87 corresponding to the circumference of a pin 81,83 includes a central opening 82. The holes extend in a direction that is parallel to the longitudinal axis of the pin (see Fig. 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 7-9, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vincent et al. (5,007,935).

Vincent et al. disclose the claimed invention except for the fixing means comprising a wire element or the fixing means comprising two or more screws. The use of wire elements and/or multiple screws instead of a single screw is a functionally equivalent means of retaining a joint coupling element, known in the art (see, e.g. Lin [5,376,126; cited by applicant]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute cables and/or multiple screws for a single screw, since doing so involves nothing more than the substitution of functionally equivalent prosthesis retaining means known in the art. With regard to claims 7-9, it also would have been obvious to form the pin at an angle less than 125 degrees, between 125 degrees and 145 degrees, or at an angle greater than 145 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. With regard to claim 12, it also would have been obvious to form the device from a shape-memory metal since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.



D.C. Comstock
8 August 2003



EDUARDO C. ROBERT
PRIMARY EXAMINER